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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,299	04/05/2005	Maxwell Edmund Whisson	05-296	3011
34704	7590	04/20/2006	EXAMINER	
BACHMAN & LAPOINTE, P.C. 900 CHAPEL STREET SUITE 1201 NEW HAVEN, CT 06510			SMITH, PAUL B	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/530,299

Applicant(s)

WHISSON ET AL.

Examiner

Paul B. Smith

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-31 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. AU-2002951827, filed on 10/7/2002 and Application No. AU-2002953025, filed on 11/29/2002.

Specification

2. The disclosure is objected to because of the following informalities:
3. On page 1 line 6, the sentence is unclear because there is no period signifying a sentence end. The suggested revision would be, "The present invention relates to a needle apparatus."
4. On page 1 line 9, "a" is capitalized in the middle of a sentence.
5. On page 8 line 23, it is unclear what the phrase "the or each finger" means. Clarification of this phrase is requested.

Appropriate correction is required.

Claim Objections

6. Claim 26 is objected to because of the following informalities: In line 1 of the claim, "a" is missing from in-between "method" and "operating". Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. The term "short" in claim 23 is a relative term, which renders the claim indefinite. The term "short" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 16-20 and 23-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon ('849).

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12. As to Claims 16 and 28-31, Yoon discloses a retractable safety-penetrating instrument comprising a sleeve (42), a needle (36), a hub (24) and a catheter introducer (22). The sleeve is disposed about the needle such that the needle remains at least partially within the sleeve at all times. The needle and sleeve are longitudinally movable relative to each other. The needle is mounted to the hub such that they move together longitudinally. The proximal end of the sleeve is located within the hub and longitudinally movable relative to the hub. Further, a first and a second position are disclosed whereby in said first position the needle extends beyond the distal end of the sleeve and in said second position the sleeve extends beyond the distal end of the needle. The catheter introducer comprises a sheath (26) and a port (28). The needle and sleeve are positioned within the port and sheath such that the needle extends beyond the sheath. Upon insertion the sheath enters the tissue relatively simultaneously as the needle and sleeve. The catheter introducer can be manually held in place in the tissue as the needle and sleeve are removed so that the catheter introducer is left in the tissue for introduction of longer devices. (See Figure 2 and 3)

13. As to Claim 17, the claim further limits the functionality of the apparatus of claim 16 but does not provide any structural limitations. As such, the instrument of Yoon is reasonably capable of withdrawing the sleeve from the tissue by application of further longitudinal traction to the hub.

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14. As to Claim 18-20, Yoon discloses a laterally extending disc shaped projection (110) from said sleeve located at the proximal end of the sleeve and means of positively engaging (114) said projection to restrain the sleeve in the second position. (See Figure 3)

15. As to Claim 24, the needle of the apparatus of Yoon is inherently in the fluid flow path of the apparatus at all times.

16. As to Claim 25, it is inherent in the apparatus of Yoon that pressure is applied directly to the sleeve from surround tissue upon insertion and retraction from a body.

17. As to Claim 26-27, Yoon teaches a method of using the disclosed apparatus comprising the following steps; piercing tissue with the needle, inserting needle and sleeve relatively simultaneously, applying longitudinal traction to the hub to withdraw the needle and withdrawing the sleeve by further applying longitudinal traction to the hub.

18. Thus it appears that Yoon reasonably appears to teach every element of claims 16-20 and 23-31.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon ('849) in view of Yoon ('176).

22. Yoon ('849) discloses a retractable safety-penetrating instrument comprising a sleeve (42), a needle (36) and a hub (24). The sleeve is disposed about the needle such that the needle remains at least partially within the sleeve at all times. The needle and sleeve are longitudinally movable relative to each other. The needle is mounted to the hub such that they move together longitudinally. The proximal end of the sleeve is located within the hub and longitudinally movable relative to the hub. Further, a first and a second position are disclosed whereby in said first position the needle extends beyond the distal end of the sleeve and in said second position the sleeve extends beyond the distal end of the needle. (See Figure 2 and 3)

23. Yoon ('849) discloses a laterally extending disc shaped projection (110) from said sleeve located at the proximal end of the sleeve and means of positively engaging (114) said projection to restrain the sleeve in the second position. (See Figure 3)

24. Yoon ('849) fails to disclose at least one finger arranged to engage with the projection in the second position.

25. Yoon ('176) teaches using a locking finger (86) to engage a substantially flat base (82). (See Figure 3)

26. It would have been obvious to one of ordinary skill in the art at the time of invention to combine the apparatus of Yoon ('849) with the locking finger of Yoon ('176) to provide a means for engaging the projections in a second position and thereby prevent sleeve movement.

Conclusion

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. U.S. Patent 5,772,678 to Thomason *et al.*
- b. U.S. Patent 5,263,937 to Shipp
- c. U.S. Patent 5104382 to Brinkerhoff *et al.*

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Smith whose telephone number is 571-272-6022. The examiner can normally be reached on 8 am - 4 pm.


29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PBS
April 14, 2006


NICHOLAS D. LUCCHESI
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Paul B Smith
Examiner
Art Unit 3763